

**New Jersey Department of Health and Senior Services
Office of Boards and Council / Institutional Review Board
PO Box 360
Trenton, NJ 08625-0360
609-292-9382**

STATE USE ONLY

ID #:

Date Rec'd:

**REQUEST FOR REVIEW AND CLEARANCE OF A PROJECT
INVOLVING HUMAN SUBJECTS**

Submit this completed form, along with 13 copies (Full Board) or 2 copies (Expedited Review) of the protocol and supporting documents to the Office of Boards and Council at the above address.

Title of Protocol	
Name of Principal Investigator	Telephone Number
Title of Principal Investigator	E-Mail Address
Name of Institution	
Address	
Name and Title of Department of Health and Senior Services Collaborator, if included in study and different from Principal Investigator	
Address	
Telephone Number	E-Mail Address
Proposed Dates for Project:: Beginning: _____ Ending: _____	
Assurance of Confidentiality The undersigned hereby agrees to the following terms and conditions related to a request for approval for research: 1. No data will be published or released in any form if a particular individual supplying the information or described in it is identifiable. 2. The identifying information will be used only for statistical purposes in medical and health research. 3. The identifying information will not be used as a basis for legal, administrative, or other actions which may directly affect those particular individuals as a result of their specific identification in this project. 4. The identifying information will be used only for the study or project proposed and the purposes described in the attached document. Use of the information for a research project other than the one described will not be undertaken until after a separate request is made to the New Jersey Department of Health and Senior Services. 5. While identifiers still appear, access to paper, hardware, and software will be secured. Paper records will be kept in locked cabinets and computers will be kept locked or have password protection. 6. All statements made to the New Jersey Department of Health and Senior Services are correct.	
Signature of Principal Investigator	Date
Name of Requester, if different from Investigator	Title
Signature of Requester	Date

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1. Name(s) of any other IRBs reviewing this project. If any of these IRBs has a multiple assurance on file with the Office of Human Research Protections, please attach a copy of the IRB approval and give the MPA number of the IRB:

2. Summarize the study protocol or project activities. Indicate specifically the ways data will be collected and used.

3. List the potential risks to study participants.

4. List any potential benefits to study participants and/or to society.

5. Do your subjects include any of the following:

- a. Infants or children younger than 10 years of age? ☐ Yes ☐ No
- b. Institutionalized mentally infirm people? ☐ Yes ☐ No
- c. Inmates/Prisoners? ☐ Yes ☐ No

Since these subjects - and others like them who are either not competent or not free to give their own consent - are particularly vulnerable to coercion and undue influence, investigators must incorporate safeguards in the research plan, and be certain to document fully their informed consent or the informed consent of their legal representatives.

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6. Informed consent must be obtained from the subjects or, in the case of children, the parent or legal guardian. Do you intend to use an informed consent form?

☐ Yes

☐ No

If yes, please enclose a copy of the form, which should include all of the elements mentioned in the instruction booklet, "Procedures for Obtaining Review by the Institutional Review Board." ALL SUBJECTS MUST KNOW THAT THEY CAN SAY "NO." If you DO NOT intend to use a consent form, please explain your reasons here:

7. In what form and to whom will the results of your study or activities be released?

8. Describe how your organization will store and maintain the confidentiality of the IDENTIFYING INFORMATION.

9. Describe the disposition of identifying information (method and intended time frame).

10. Is there any other information that the IRB would find useful? If so, please describe: